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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,623	03/10/2004	Edward I. Wulfman	89000.3013NP	6167

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SPECKMAN LAW GROUP PLLC
1201 THIRD AVENUE, SUITE 330
SEATTLE, WA 98101

EXAMINER	
HORNBERGER, JENNIFER LEA	
ART UNIT	PAPER NUMBER
3734	
MAIL DATE	DELIVERY MODE
12/23/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/798,623	WULFMAN ET AL.	
	Examiner	Art Unit	
	JENNIFER L. HORNBERGER	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 August 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-5,10 and 16-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-5,10 and 16-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

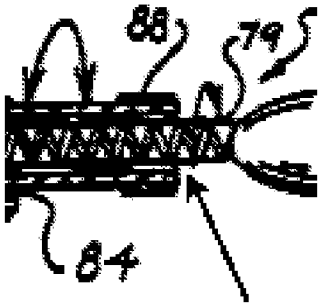
2. Claims 2-5, 10, 16-21, 26, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Keith et al. (US 5,938,670).

Regarding claim 18, Keith et al. disclose an intracorporeal medical device having a rotatable torque tube (42) and a sealing assembly (79) for creating a liquid seal around the torque tube during operation of the device, the sealing assembly comprising a housing (114) enclosing at least a portion of the torque tube in a manner that permits free rotation and axial translation of the torque tube (col. 8, ln. 45-48 and ln. 63-65), the housing including an infusion port (36; 126) providing a sealing liquid; and a liner (79) surrounding the rotatable torque tube in the area of the infusion port and extending longitudinally less than the axial length of the torque tube (col. 12, ln.7-10), the liner forming a flood space within the inner surface of the liner whereby the sealing liquid enters the flood space and prevents air from entering the space external to the torque tube during operation of the device (col. 12, ln. 3-34).

Regarding claim 19, Keith et al. disclose an aspirating catheter device having a liquid seal assembly for creating a liquid seal in a medical device, the aspirating catheter system comprising: a torque tube (42) operably connected to a drive system for rotation (col. 6, ln.45-49); a liner (79) surrounding the rotatable torque tube to form a liquid flood space between the

liner and the torque tube (col. 12, ln. 3-34), the liner extending longitudinally less than the axial length of the torque tube and terminating at an intersect area (defined as the area shown in figure below) (col. 12, ln. 7-10); a catheter (70) enclosing the torque tube and the liner and extending distally (with respect to the occlusion) beyond the intersect area, the catheter forming an aspiration lumen (80) between the catheter and the liner; whereby liquid drawn into the flood space during operation of the catheter system exits the flood space at the intersect area and enters the aspiration lumen.

Regarding claim 20, Keith et al. disclose a medical device comprising: a rotatable torque tube (42) operably connected to a drive system for rotation (col. 6, ln. 45-49) and a liner (79) surrounding the torque tube and forming a flood space extending from a sealing assembly along at least a portion of the torque tube to an intersect area (defined as the area indicated by the arrow in the figure below); a catheter (70) enclosing at least a portion of the torque tube and the liner (79) and forming an aspiration lumen (80) between the catheter and the liner, the catheter enclosing the intersect area of the liner; and a sealing assembly in communication with an infusion port (126) providing application of liquid to the flood space during operation of the device.



Regarding claim 2, Keith et al. disclose the flood space includes a clearance area between the liner and the torque tube.

Regarding claim 3, Keith et al. disclose the torque tube is a coiled drive shaft and the flood space includes gaps between the coils (Fig. 3,4).

Regarding claim 4, Keith et al. disclose the torque tube (42) includes a lumen (43) for a guidewire (45) and the flood space includes the lumen.

Regarding claim 5, Keith et al. disclose a suction port (76) for aspirating fluid from a lumen (80) (col. 10, ln. 46-53) and wherein the liner separates a lower pressure in the flood space from adjacent higher pressure outside or proximal to the flood space (col. 11, ln. 65-67).

Regarding claim 10, Keith et al. disclose the sealing member further comprises an overflow port (sealing bearing 56) for exit of excess liquid and wherein the torque tube extends through the overflow port.

Regarding claim 16, Keith et al. disclose a drive system (10) coupled to the torque tube to rotate the torque tube.

Regarding claim 17, Keith et al. disclose a hand held unit and the sealing assembly housed within the hand held unit.

Regarding claim 21, Keith et al. disclose the pressure within the flood space decreases along the length of the liner in a distal direction during operation of the device (col. 12, ln. 11-34).

Regarding claim 26, Keith et al. disclose proximal portions of the torque tube and liner are positioned in a housing in a manner that permits free rotation and axial translation of the torque tube (col. 8, ln. 45-48 and ln. 63-65).

Regarding claim 27, Keith et al. disclose the length and diameter of the liner forming the flood space are selected to reduce the rate of flow in the proximal to distal direction in the flood space and reduce the requirement for precise diametrical tolerances during operation of the device (col. 12, ln. 11-34).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 22, 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keith et al. (US 5,938,670).

Regarding claim 22, Keith et al. fail to disclose the inner diameter of the liner is from about 0.030 to about 0.040 inch. Keith discloses the diameter of the guidewire up to .020 inches (col. 19, ln. 19). It would have been obvious to one having ordinary skill in the art at the time the invention was made to optimize the diameter of the liner to at least accommodate the guidewire, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Regarding claim 23, Keith et al. disclose the claimed invention except for the liner length being more than about 6 inches. It would have been obvious to one having ordinary skill in the art at the time the invention was made to optimize the length of the liner, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

5. Claims 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keith et al. (US 5,938,670) in view of Milo (US 6,258,052) and Machold et al. (US 4,976,720).

Regarding claims 24 and 25, Keith et al. is silent as to the material of the liner. Milo discloses a polyimide tube in contact with a coiled wire or shaft increases pushability and column strength (col. 2, ln. 61 - col. 3, ln. 2). It would have been obvious to one of ordinary skill to have tried making the liner of polyimide tubing to provide the same advantages to the coiled torque tube of Keith et al. to prevent buckling during vascular occlusion ablation. Keith et al. in view of Milo fail to disclose a lubricious coating. Machold et al. disclose a polyimide tube having a lubricious coating (col. 5, ln. 3-4). It would have been obvious to one of ordinary skill in the art provide a lubricious coating on the outside of the polyimide liner to reduce friction between the drive shaft and the lumen of catheter (70).

Response to Arguments

6. Applicant's arguments filed 08/20/2008 have been fully considered but they are not persuasive. Applicant argues that the sheath (79) of Keith et al. does not constitute a liner and that the sealing assemblies of the present invention are not conventional infusion systems. While applicant relies on the fact that Keith's infusion system is not the same as the sealing assemblies of the instant applicant, the structure and function of sealing assembly which distinguishes the two systems have not been claimed. The sheath (79) of Keith et al. meets the limitations of the “liner” in that it surrounds the torque tube (42) in the area of the infusion port,

forming a flood space whereby sealing liquid enters the flood space creating a liquid seal in that it seals the torque tube (42) and provides a greater resistance to fluid flow and slowing fluid loss (col. 12, ln. 23-34).

7. Applicant further argues that the sheath (79) of Keith et al. is not shorter than the length of the torque tube. However, Keith et al. discloses that the torque tube (42) extends proximally beyond element (54; col. 9 ,ln. 46-49) and that the sheath (79) stops adjacent to the distal end of element 56 (col. 12, ln. 8-10). Therefore, the sheath (79) extends longitudinally less than the axial length of the torque tube.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER L. HORNBERGER whose telephone number is (571)270-3642. The examiner can normally be reached on Monday through Friday from 8am-5pm, Eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571)272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

jlh
12/16/2008

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3731